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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,173	09/09/1999	DAVID T. CUIEL	D6163	2338

27851 7590 03/19/2003

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.
09/393,173

Applicant(s)
Curiel et al.

Examiner
Anne Marie Wehbé

Art Unit
1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Feb 11, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____
- Claim(s) objected to: _____
- Claim(s) rejected: 1-3 and 5-10
- Claim(s) withdrawn from consideration: _____
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

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ATTACHMENT TO ADVISORY ACTION

1. The applicant states on page 5 of the response that claims 1-2 have been canceled. However, there is no record of the applicant ever having requested the cancellation of these claims. The instant response only requests the amendment of claims 3, 7, and 9. As such, claims 1-2 are still considered pending.

2. Since claims 1-2 are pending, the rejection of claims 1-2 under 35 U.S.C. 103(a) is maintained.

3. The rejection of claims 2-3 and 5-10 under 35 U.S.C. 112, first paragraph, is maintained in modified form for reasons of record. In view of the applicant's declaratory data, the scope of enablement is as follows: the specification is only enabling for methods of treating glioma by intratumoral administration of an inducible recombinant adenovirus encoding a pro-apoptotic bax gene which is placed downstream of a loxP excision cassette and the intratumoral administration of an adenoviral vector encoding cre recombinase followed by the administration of radiation. The applicant's declaratory data, Figure 1, clearly demonstrates that the intratumoral administration of the inducible Ad/bax and Ad/cre alone in the absence of radiation has no effect on tumor growth *in vivo*. Therefore, applicant's claims 3-8 clearly lack an essential element necessary for successful treatment of a tumor. Furthermore, the applicant's data is limited to the intratumoral administration of the adenoviral vectors. The specification provides no support for alternative

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routes of administration. Further, the art at the time of filing as cited in previous office actions teaches the unpredictability in achieving therapeutic levels of gene expression in target cells using various vectors and routes of administration. Thus, the specification in view of the declaratory data provided does not enable the breadth of the subject matter in applicant's claims and is limited to the scope identified above.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

